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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-------------------------|
| 09/966,421 | 09/27/2001 | Syed F.A. Hossainy | 50623.60 | 6381 |
| 7590 | 05/18/2005 | | EXAMINER | |
| Squire, Sanders & Dempsey, L.L.P. Suite 300 One Maritime Plaza San Francisco, CA 94111 | | | NGUYEN, VI X | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |
| | | | | DATE MAILED: 05/18/2005 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/966,421 | HOSSAINY, SYED F.A. |
| | Examiner Victor X Nguyen | Art Unit 3731 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 February 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8,10-13,29-32 and 45-72 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-8,10-13,29-32 and 45-72 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 03/2005.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-8,10-13,29-32 and 45-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claims 1 and 45, line 2, the disclosure corresponding to **election of Group 1, Specie 3 of figure 6 (elected without traverse on 6/11/2003)** does not describe a stent body or a radially expandable stent body as recited. Clarification is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 11-13, 45, 47-50 and 54-60 are rejected under 35 U.S.C. 102 (e) as being anticipated by Ten Cate (U.S.6,352,683).

Ten Cate shows in figures 3-4, a stent or other implantable medical device that releases drug into the vascular system having the limitations of claims 1 and 45, including: a first material (labeled in col.6, lines 1-11) carrying a therapeutic substance. A second material (col.2, lines 1-

14) configured to convert a first type of energy to a second type of energy. In fact, Ten Cate discloses that the drug delivery system is characterized by the combination of a carrier material which reflects or absorbs or emits electromagnetic waves for delivering the carrier material and the drug to a specific site. Ten Cate does so to indicate that the electromagnetic waves are intended to comprise heat which are reflected or emitted in the form of energy through a space or through a material medium (see col. 5, lines 3-11). Regarding the intended use of a stent for delivering a therapeutic substance; a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the device of Ten Cate would have been capable of performing the use as claimed.

Regarding claims 2-4 and 47-49, where the second material is selected from the group consisting of Au particles (labeled in col.2, lines 1-8). The second type of energy is thermal energy; and wherein the second material is disposed in microdepots or mircroparticles (col. 2, lines 14-20).

Regarding claims 5-6 and 50, where a topcoat (20) deposits over a portion of the first material; and wherein the second material includes Au particles (col. 2, lines 1-8).

Regarding claims 7-8 and 54-55 ,Ten Cate discloses that the device as seen on fig. 3 is capable of using more than one materials configured to convert more than one energy (see col. 11 , lines 12-34).

Regarding claims 11-13 and 56-58, where the first material is hydrogel (col. 6, lines 10-11) which is selected from polypeptides and mixtures thereof (col. 12, lines 45-65 and col. 13,

lines 1-20). Regarding claims 31-32 and 59-60, Ten Cate discloses the hydrogel characteristic as claimed in col. 6, lines 8-54).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-30 and 51-53 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ten Cate' 683. Ten Cate is silent regarding the diameter of Au particles having a silica nanoparticle from 100 to 250 nm or having a thickness of 1 to 100 nm. Nevertheless, Ten Cate does disclose Au particles, which must be changed in the size of a component involve merely routine skill in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make Ten Cate' the diameter of Au particles having a silica nanoparticle from 100 to 250 nm or having a thickness of 1 to 100 nm. Regarding claims 10 and 46, it would have been further obvious to one having ordinary skill in the art at the time the invention was made to have electromagnetic waves with wave lengths between 800 and 1200 nm into thermal energy, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Art Unit: 3731

5. Applicant's arguments filed 2/28/2005 have been fully considered but they are not persuasive. the applicant argues that Ten Cate reference fails to show certain feature of applicant's invention, it is noted that the feature upon which applicant relies (i.e., a second material **configured to convert non-cytotoxic electromagnetic waves received by the second material to a second type of energy**) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that Ten Cate does not teach "the particles of Ten Cate could not perform the same function as the present invention" is a functional limitation. Thus, a reference needs not show the structure of the recitation in order to meet the claim language but rather the reference needs only be capable of being used with such structure. Accordingly, the above noted reference is still considered to read on the claimed limitations of the claims noted.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen
Examiner
Art Unit 3731

Vn VN
5/13/2005



JULIAN W. WOO
PRIMARY EXAMINER